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☐	L4	L2 and (zone or zones or regions or region or place or dot or locat$ or position$).clm.	588
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☐	L6	L5 and (read$ or computat$ or microchip$).clm.	27
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☐	L9	zone.clm. and analyte.clm. and lip.clm.	0
☐	L10	zone.clm. and lip.clm.	1220
☐	L11	L10 and (detect$ or measur$ or test$ or determin$ or unknown$).clm.	153
☐	L12	L11 and (read$ same (device or apparatus)).clm.	3
☐	L13	L1 and analyte.clm.	10
☐	L14	cass.in.	405
☐	L15	L14 and device.clm.	42
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US005869972A

United States Patent [19]

Birch et al.

[11] Patent Number: 5,869,972

[45] Date of Patent: Feb. 9, 1999

[54] **TESTING DEVICE USING A THERMOCHROMIC DISPLAY AND METHOD OF USING SAME**

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[21] Appl. No.: **807,008**

[22] Filed: **Feb. 26, 1997**

[30] **Foreign Application Priority Data**

Feb. 26, 1996 [EP] European Pat. Off. 96301259

[51] **Int. Cl.**[6] **G01N 33/18**; G01N 33/48

[52] **U.S. Cl.** **324/439**; 324/441; 324/450; 250/564; 422/56; 422/82.02

[58] **Field of Search** 324/438, 439, 324/450, 692, 693, 713, 717, 722; 422/55, 56, 82.01, 82.02, 82.05; 436/66, 67, 68, 169; 250/564; 128/632, 633, 636, 637, 748, 771; 204/400, 402, 403; 600/309, 365, 367, 368, 561, 584

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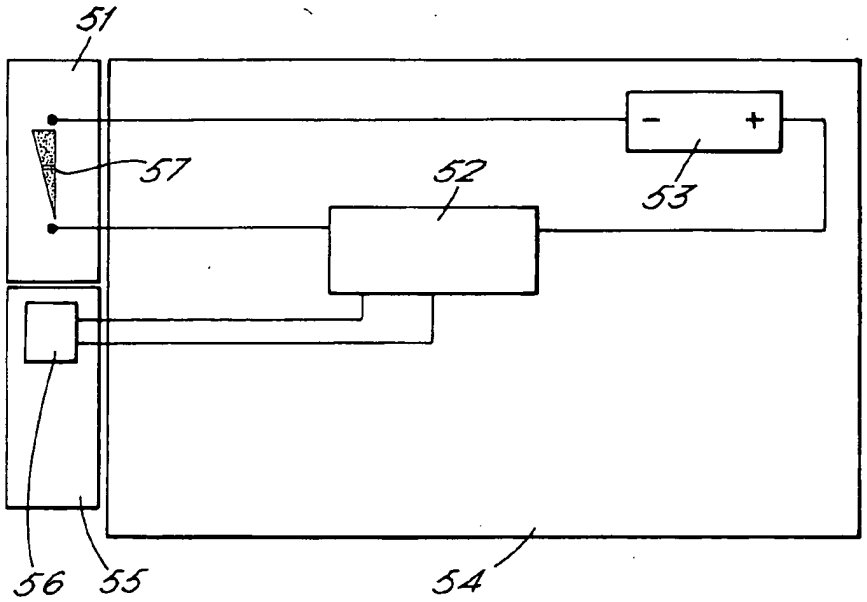
Primary Examiner—Josie Ballato
Assistant Examiner—Diep Do
Attorney, Agent, or Firm—Pillsbury Madison & Sutro LLP

[57] **ABSTRACT**

A testing device for qualitatively or quantitatively sensing an electrochemical or analogous reaction at the surface of a test strip (**46**), the current flowing or charge accumulated at the test strip being processed by electronics (**50**) to generate a current signal suitable for activating a display (**52**) typically in the form of a thermochromic layer.

12 Claims, 4 Drawing Sheets



sensing modules **62** each with an associated display module **64**, which correspond generally to modules **51** and **55** of FIG. **6**. In use, unit **60** is connected to the sensing module and associated display module at one end of the array, as illustrated schematically by arrow **66**, and the test is performed as described above. The modules used may then be separated from the remainder of the array. The sensing module will generally be disposed of after use, and the display module may either be disposed of with the sensing module or may be separated from the sensing module and retained for record purposes. To this end, the display modules each carry a unique, preferably machine-readable, identifier **68** such as a bar code. The bar code could be read by the electronic components and recorded in a computer readable format for additional processing be the said electronics or by external facilities. The bar codes could incorporate a code to identify the analytes that can be measured or the actual performance characteristics of the particular batch being used. Instead of bar codes other known forms of coding such as shades of colour, diffracting grating characteristics or passive electronic components or others known to those skilled in the art could alternatively be used.

The tester may be employed for a variety of purposes, such as sensing oxido-reductase reactions which result in current flow or changes in chemical potential at electrode surfaces. Examples are GODFAD/FADH2, or enzymes which employ NAD/NADH2 or NADP/NADPH2 systems. In potentiometry, it is possible qualitatively or quantitatively to sense any chemical reaction which changes the electrochemical potential at the surface of an electrode in a manner that reflects the concentration of the analyte. This could include schemes based upon inhibition principles as well as the usual forms of determination. It is possible for the test strip to carry a substance which promotes the reaction (when the test strip is disposable). The electro-chemical reaction may be associated with antibody-antigen reactions (Ab-Ag) for electrochemical linked immuno assays.

Moreover, the tester can be applied to optical assay systems, such as in any of the foregoing examples, but with optical detection and transduction.

We claim:

1. A testing device for use in determination of a particular characteristic of a fluid, comprising a sensing element for contacting the fluid and producing a response indicative of the characteristic to be determined, electronic means for processing the response to produce an electrical signal of magnitude indicative of the characteristic, and a display device comprising a conductive track for passing a current the magnitude of which is dependent on the magnitude of the electrical signal produced by the electronic means and a thermochromic layer overlying the conductive track for changing color to a dimensional extent dependent on the magnitude of current passing in the conductive track.

2. A testing device according to claim **1**, in the form of a portable device.

3. A testing device according to claim **2**, in the form of a hand-held device.

4. A testing device according to claim **1**, further comprising a source of electrical power.

5. A testing device according to claim **1**, wherein at least the sensing element is separable from the remainder of the testing device and is disposable.

6. A testing device according to claim **1**, wherein the sensing element carries a promoter for stimulating an electrochemical reaction at the surface of a test strip.

7. A testing device according to claim **1**, wherein the display device includes a thin layer of colored material becoming transparent with generation of heat, located between the conductive track and the thermochromic layer.

8. A testing device according to claim **1**, wherein the thermochromic layer is adapted to provide an analogue read-out in the form of a bar the length of which is dependent on the magnitude of the current passing through the conductive track.

9. A testing device according to claim **1**, wherein the thermochromic layer is adapted to provide a digital read-out in the form of a number of discrete steps which is dependent on the magnitude of the current passing through the conductive tracks.

10. A method of testing a fluid for a particular characteristic thereof using a testing device, comprising the steps of contacting the fluid with the testing device to cause a sensing element to produce a response indicative of the characteristic to be determined, and electronically processing the response to produce an electrical current the magnitude of which is indicative of the characteristic, characterized by the further step of passing the electrical current through a conductive track underlying a thermochromic layer which thereby changes color to a dimensional extent dependent on the magnitude of the current.

11. A method according to claim **10**, applied to test the concentration of an analyte in a solution by sensing an electrochemical reaction at the surface of an electrode on the sensing element.

12. A testing device for use in determination of a particular characteristic of a fluid, comprising a sensing element having electrodes for contacting the fluid, means whereby a current signal is caused to pass between the electrodes when the sensing element is in contact with the fluid, the magnitude of said current signal being representative of the fluid characteristic to be determined, electronic means for processing the current signal to produce a display signal, and a display device for receiving the display signal, whereby to produce a visual indication of the fluid characteristic to be determined, said display device comprising a conductive track for passing the display signal and a thermochromic layer overlying the conductive track for changing color to a dimensional extent dependent on the magnitude of the display signal.

* * * * *

labels materials which block or reflect the electromagnetic radiation, rather than absorb it, e.g. "white" particles such as latex particles in their natural uncoloured state. Alternatively, the label can be a reactant or catalyst which participates in the generation of a radiation absorbing or radiation-blocking material, e.g. an enzyme which reacts with a substrate to produce a detectable material, such as a coloured material, in the detection zone.

EXAMPLE

The purpose of this example is to confirm that the transmission reading system of the invention enables consistent data to be obtained from a testing device.

A dual-analyte testing device, selected at random from a batch of identical devices constructed as hereinbefore described with reference to FIGS. **1** and **2**, using blue-coloured latex particles as a label concentrated in two test lines on a nitrocellulose strip to reveal the test result, was repeatedly inserted and "read" in a monitor constructed as hereinbef ore described with reference to FIGS. **3** to **8**.

The intensities of the two test lines respectively represented the concentrations of LH and E3G in a urine sample applied to the testing device.

The testing device was inserted and removed from the monitor 10 times. The percentage light transmission for each reading was as follows:

	LH	E3G
	44.0	39.3
	43.8	39.3
	43.8	39.5
	43.8	39.3
	43.8	39.3
	43.9	39.4
	43.8	39.2
	43.9	39.2
	43.9	39.2
	43.9	39.4
Mean:	43.9	39.3
sd:	0.1	0.1
cv%	0.2%	0.3%

These results indicate that the reading system of the invention produces consistent data which is not affected significantly by any variability of test line placement when the test device is inserted in the monitor.

What is claimed is:

1. An assay result reader, for use in conjunction with an assay device which comprises a porous liquid-permeable carrier in the form of as trip or sheet through the thickness of which electromagnetic radiation is transmissible, said carrier including a detection zone in which an assay result is revealed by specific binding of a detectable material directly or indirectly to a binding agent immobilized in said detection zone, detection of said detectable material being effected by determining the extent to which electromagnetic radiation transmitted through the thickness of said carrier is attenuated by the presence of said detectable material bound in said detection zone, said assay result reader comprising:

a) receiving means for receiving at least a portion of said assay device, said portion including said detection zone;

b) reading means associated with said receiving means said reading means comprising:

(i) at least one source of electromagnetic radiation;

(ii) one or ore sensors capable of detecting the intensity of said electromagnetic radiation, said source and said one or more sensors being positioned such that when said portion of said assay device is received within said receiving means, said detection zone is disposed in the electromagnetic radiation path between said source and said one or more sensor; and

(iii) a diffuser in froni of said one or more sensors and downstream of said assay device such that electromagnetic radiation from said source must pass through said diffuser before reaching said one or more sensors, said detection zone of said assay device being disposed in the electromagnetic radiation path between said source and said diffuser when said assay device is received within said receiving means.

2. An assay result reader according to claim **1**, wherein said electromagnetic radiation is light.

3. An assay result reader according to claim **2**, wherein said light is visible light.

4. An assay result reader according to claim **1**, wherein said radiation is pulsed and said one or more sensors are synchronized so that they function only in phase with the pulsed radiation.

5. An assay result reader according to claim **4**, wherein said radiation has a pulse frequency of at least about 1 kHz.

6. A test kit comprising an assay result reader according to claim **1**, together with said assay device comprising a porous liquid-permeable carrier strip or sheet through the thickness of which electromagnetic radiation is transmissible, said carrier including said detection zone in which an assay result is revealed by specific binding of a detectable material directly or indirectly to a binding agent immobilized in said detection zone.

7. A test kit according to claim **6**, wherein said assay result reader includes said receiving means for receiving at least a portion of said device, said portion including said detection zone, to present said detection zone to said reading means comprising said electromagnetic radiation and said one or more sensors located such that upon insertion of said device into said receiving means, electromagnetic radiation can be passed through said device and the intensity of electromagnetic radiation emerging from said device can be detected by said one or more sensors.

8. A test kit as claimed in claim **7**, wherein said receiving means incorporates interlocking means engageable with corresponding interlocking means on said device to ensure that upon receipt of said device by said reader said at least one detection zone is located and maintained in a predetermined spatial relationship relative to said reading means.

9. A test kit as claimed in claim **8**, wherein said receiving means includes actuating means triggered by said receipt of said device, said actuating means causing said reading of said at least one detection zone to be initiated.

10. A test kit according to claim **6**, wherein said electromagnetic radiation is light.

11. A test kit according to claim **10**, wherein said light is visible light.

12. A test kit as claimed in claim **6**, wherein said detectable material comprises a particulate direct label.

13. A test kit as claimed in claim **12**, wherein said electromagnetic radiation is visible light of a wavelength that is strongly absorbed by said particulate direct label.

14. A test kit according to claim **6**, wherein said assay device is one of a plurality of identical such devices provided as part of the kit.

15. A test kit comprising an assay result reader together with an assay device comprising a porous liquid-permeable

carrier in the form of a strip or sheet through the thickness of which electromagnetic radiation is transmissible, said carrier including a detection zone in which an assay result is revealed by specific binding of a detectable material directly or indirectly to a binding agent immobilized in said detection zone, detection of said detectable material being effected by determining the extent to which electromagnetic radiation transmitted through the thickness of said carrier is attenuated by the presence of said detectable material bound in said detection zone, said assay result reader comprising:

a) receiving means for receiving at least a portion of said assay device, said portion including said detection zone:

b) reading means associated with said receiving means, said reading means comprising:

(i) at least one source of electromagnetic radiation; and

(ii) one or more sensors capable of detecting the intensity of said electromagnetic radiation, said source and said one or more sensors being positioned such that when said portion of said assay device is received within said receiving means, said detection zone is disposed in the electromagnetic radiation path between said source and said one or more sensors; and

(iii) a diffuser in front of said one or more sensors such that electromagnetic radiation from said source must pass through said diffuser before reaching said one or more sensors said detection zone of said assay device being disposed in the electromagnetic radiation path between said source and said diffuser when said assay device is received within said receiving means and

wherein said carrier of said assay device is within a casing or cover forming part of said assay device, and said casing or cover having electromagnetic energy transmitting regions enabling electromagnetic radiation to be passed through said device, said detection zone lying in the electromagnetic radiation path between said transmitting regions.

16. A test kit as claimed in claim 15, wherein said device casing or cover includes internal registration means which engages with corresponding registration means associated with said carrier such that said detection zone within said device casing or cover is located in a predetermined spatial relationship relative to interlocking means on said device casing or cover.

17. A test kit according to claim 16, wherein said internal registration means comprises a pin or the like, engageable with a hole or indentation in said carrier, said detection zone being at a predetermined location on said carrier relative to said hole or indentation.

18. A test kit according to claim 15, wherein said electromagnetic radiation from said source is pulsed.

19. A test kit comprising an assay result reader together with an assay device comprising a porous liquid-permeable carrier in the form of a strip or sheet through the thickness of which electromagnetic radiation is transmissible, said carrier including a detection zone in which an assay result is revealed by specific binding of a detectable material directly or indirectly to a binding agent immobilized in said detection zone, detection of said detectable material being effected by determining the extent to which electromagnetic radiation transmitted through the thickness of said carrier is attenuated by the presence of said detectable material bound in said detection zone, said assay result reader comprising:

a) receiving means for receiving at least a portion of said assay device, said portion including said detection zone;

b) reading means associated with said receiving means, said reading means comprising:

(i) at least one source of diffuse electromagnetic radiation; and

(ii) one or more sensors capable of detecting the intensity of said electromagnetic radiation, said source and said one or more sensors being positioned such that when said portion of said assay device is received within said receiving means, said detection zone is disposed in the electromagnetic radiation path between said source and said one or more sensors; and

(iii) a diffuser in front of said one or more sensors such that electromagnetic radiation from said source must pass through said diffuser before reaching said one or more sensors, said detection zone of said assay device being disposed in the electromagnetic radiation path between said source and said diffuser when said assay device is received within said receiving means

wherein said carrier strip or sheet comprises nitrocellulose having a thickness not exceeding 1 mm.

* * * * *

US006235241B1

(12) **United States Patent**
Catt et al.

(10) **Patent No.: US 6,235,241 B1**
(45) **Date of Patent: May 22, 2001**

(54) **READING DEVICES AND ASSAY DEVICES FOR USE THEREWITH**

(75) Inventors: **Michael Catt**; **Paul Henry Mundill**; **Michael Evans Prior**, all of Northampton (GB)

(73) Assignee: **Unipath Limited**, Basingstoke Hampshire (GB)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/078,501**

(22) Filed: **May 14, 1998**

Related U.S. Application Data

(62) Division of application No. 08/338,141, filed on Nov. 9, 1994.

(30) **Foreign Application Priority Data**

Nov 12, 1993 (EP) 93309053

(51) **Int. Cl.**[7] **G01N 21/00**
(52) **U.S. Cl.** **422/56**; 422/82.05; 422/82.09
(58) **Field of Search** 422/82.05, 82.09, 422/61, 56, 57, 58; 356/432, 443

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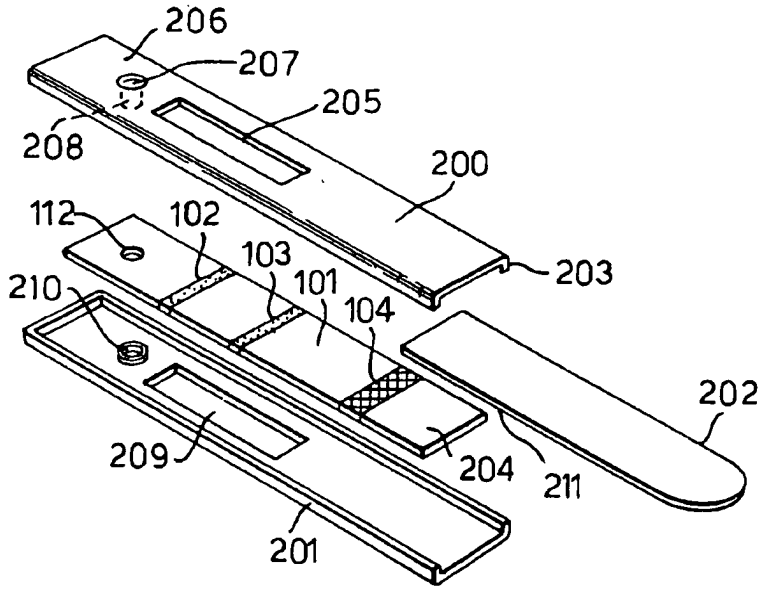
Primary Examiner—Elizabeth McKane
(74) *Attorney, Agent, or Firm*—Pillsbury Wintrop LLP

(57) **ABSTRACT**

An assay result reader, for use in conjunction with an assay device comprising a porous liquid-permeable carrier in the form of a strip or sheet through the thickness of which electromagnetic radiation is transmissible, the carrier including a detection zone in which an assay result is revealed by specific binding of a detectable material directly or indirectly to a binding agent immobilized in the detection zone, detection of the detectable material being effected by determining the extent to which electromagnetic radiation transmitted through the thickness of said carrier is attenuated by the presence of the detectable material bound in the detection zone.

19 Claims, 7 Drawing Sheets



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Terms	Documents
L2 and (analyte or antigen or antibody or hcg or estrogen or hlh or pregnancy or substance).ti,ab,clm.	24

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US006451619B1

(12) **United States Patent**
Catt et al.

(10) **Patent No.: US 6,451,619 B1**
(45) **Date of Patent: *Sep. 17, 2002**

(54) **MONITORING METHODS AND DEVICES FOR USE THEREIN**

(75) Inventors: **Michael Catt**, Northampton; **Carole R Cunningham**, Bedford; **Paul HC Mundill**, Northampton; **Michael E Prior**, Northampton; **Stewart Wilson**, Northampton; **Zhi G Zhang**, Bedford, all of (GB)

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(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **08/532,457**

(22) Filed: **Sep. 22, 1995**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/266,776, filed on Jun. 29, 1994, now abandoned, and a continuation-in-part of application No. 08/338,141, filed on Nov. 9, 1994.

(30) **Foreign Application Priority Data**

Sep. 23, 1994 (GB) 9419264
Sep. 26, 1994 (GB) 9419382
Jan. 31, 1995 (GB) 9501863

(51) **Int. Cl.**[7] **G01N 33/543**

(52) **U.S. Cl.** **436/514**; 436/165; 436/169; 436/65; 435/7.92; 435/7.93; 435/7.94; 435/7.9; 435/7.1; 422/56; 422/58; 422/61

(58) **Field of Search** 436/514, 165, 436/169, 65; 435/7.92, 7.93, 7.94, 7.9, 7.1; 422/56, 58, 61

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(57) **ABSTRACT**

Methods, devices and test kits for monitoring the ovulation cycle, involve testing the body fluid, e.g. urinary, concentration of one or more analytes. Preferably estrone-3-glucuronide and luteinizing hormone are both measured, and a reference concentration for E3G is established at about day 6 of the current cycle. Preferably, disposable testing devices are used, in conjunction with a relatively permanent electronic reader/monitor. The number of "daily" tests required per month can be minimized.

11 Claims, 8 Drawing Sheets